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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,974	03/24/2004	Charles C. Hart	A-3124-AL	6970

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APPLIED MEDICAL RESOURCES CORPORATION
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

EXAMINER	
MEHTA, BHISMA	
ART UNIT	PAPER NUMBER
3767	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,974	HART ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-38 and 75-89* is/are pending in the application.

4a) Of the above claim(s) *10-14,16-19 and 27-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,20-26,34-38 and 75-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 1, 2010 has been entered.

Specification

2. The abstract of the disclosure is objected to because the abstract is too long. Correction is required. See MPEP § 608.01(b).

3. The use of the trademark KRATON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

4. Claims 36, 79, and 82 are objected to because of the following informalities: The use of the trademark KRATON is noted in claims 36 and 79 and it is suggested that it should be capitalized. In claim 79, the word "slilcone" is misspelled. There appears to

be a word missing before "duckbill valve" in claim 82. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 83 and 86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The septum seal comprising a bonding feature where the duckbill valve is attached to the bonding feature or for attaching the zero seal is not disclosed or supported in the specification as originally filed. In lines 7-10 of page 13, it is disclosed that a bonding feature may be provided for attaching the first seal (i.e., the septum seal) to the second seal (i.e., the duckbill sealing or zero seal). This disclosure of the specifics of the bonding feature in the specification is not support for the septum seal comprising a bonding feature as "the septum seal comprising a bonding feature" indicates that the septum seal is a bonding feature or that the bonding feature is part of the septum seal.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 87 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The wording of "the septum seal is coupled to the septum seal" appears to contain an error as it is unclear if the septum seal is being claimed to be coupled to the zero seal or the tubular member. For the purpose of examining claim 87, it is the Examiner's interpretation based on the disclosure in lines 9-18 of page 14 that the zero seal is coupled or attached to the septum seal by fusing.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 84 and 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Lafontaine (U.S. Patent No. 6,520,939)). Lafontaine disclose a surgical access device having an elongate tubular member (110) with a working channel and an axis extending between a proximal end (112) and a distal end (114) and having a seal system at the distal end of the tubular member. The seal system comprises a septum seal comprising a septum (140) having an orifice sized and configured to seal in conjunction with a specific range of usable instruments and a zero seal (130) coupled to the septum seal and being sized and configured to seal when no instrument is in place within the working channel of the tubular member as the zero seal is normally closed (Figures 5A

and 5B and lines 6-64 of column 4). As disclosed in lines 46-49 of column 4, the septum seal has an orifice which is sized and configured to provide a fluid tight seal about the devices inserted through the orifice. The zero seal is coupled or joined to the septum seal due to their positions as shown in Figures 5A and 5B and as disclosed in lines 6-22 of column 4 where Lafontaine discloses that the septum seal and the zero seal can be at a common position in the shaft of the tubular member. The zero seal is also considered to be coupled to the septum seal because the two seals are linked together as they form a seal system together or because they form a pair of seals in the seal system. As to claim 88, the septum seal and the zero seal are formed in a monolithic construction as the septum seal and the zero seal are formed to result in a singular device, i.e., the tubular member, the septum seal, and the zero seal are parts of one device.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 85-87 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Haberland et al (U.S. Patent Application Publication No. 2005/0165433). Lafontaine discloses the device substantially as claimed. Even though Lafontaine discloses the zero seal as being coupled to the septum seal as discussed

above, Lafontaine is silent on the specifics of the zero seal being coupled to the septum seal by bonding or by fusing. Haberland et al disclose a surgical access device having a seal system with a septum seal (50) and a zero seal (60) where the zero seal is coupled to the septum seal by bonding or fusing (paragraphs [0048] and [0049]). Haberland et al also disclose the septum seal comprising a bonding feature or structure (36) for attaching the zero seal to the septum seal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to couple the zero seal to the septum seal of Lafontaine by bonding and fusing as taught by Haberland et al as both Lafontaine and Haberland et al disclose a surgical access device having a seal system with a zero seal coupled to a septum seal and Haberland et al teach that it is well known to use bonding or fusing to couple the zero seal to the septum seal so that the seal system can be formed as one unit. As to claim 86, it would have been obvious to one having ordinary skill in the art at the time the invention was made to attach the zero seal to the septum seal of Lafontaine with the use of a bonding structure as taught by Haberland et al as both Lafontaine and Haberland et al disclose a surgical access device having a seal system with a zero seal coupled to a septum seal and Haberland et al teach that it is well known to use a bonding structure to attach the zero seal to the septum seal so that the seal system can be formed as one unit.

As to claim 89, even though Lafontaine discloses the device as having a septum seal comprising a septum (140) having an orifice sized and configured to seal in conjunction with a specific range of usable instruments, Lafontaine is silent on the specifics of the septum comprising an elastomeric sheet having a frusto-conical shape.

The septum seal (50) of Haberland et al comprises a septum having an orifice sized and configured to seal in conjunction with a specific range of usable instruments and comprising an elastomeric sheet having a frusto-conical shape (paragraphs [0043,] [0046] and [0047] and Figures 2, 5, 6, 9A, 10, 11, and 13). As disclosed in paragraphs [0043] and [0046], the septum comprises a sheet which is elastomeric and the septum seal (50) as a whole is disclosed as having an elastic range to readily accommodate the instruments. As seen in Figure 9A, the septum comprises an elastomeric sheet having a frusto-conical shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the septum of Lafontaine with the septum comprising an elastomeric sheet having a frusto-conical shape of Haberland et al as both Lafontaine and Haberland et al disclose a septum having an orifice which can be used to provide a seal with instruments which are passed through the orifice and, thus, the septum of Haberland et al would be a mere substitution of parts performing the same function.

13. Claims 1, 3-9, 20-24, 34, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine (U.S. Patent No. 6,520,939) in view of Haberland et al (U.S. Patent Application Publication No. 2005/0165433). Lafontaine discloses a surgical access device having an elongate tubular member (110) with a working channel and an axis extending between a proximal end (112) and a distal end (114), a septum seal (140) integrally formed at the distal end of the tubular member, and a zero seal (130) disposed at the distal end of the tubular member and distal to the septum seal. The septum seal is integrally formed at the distal end of the tubular member as

the septum seal is an integral part of the tubular member (lines 16-22 of column 4) and the septum seal and the tubular member form or are part of an integral or one-piece device. As disclosed in lines 46-49 of column 4, the septum seal has an orifice configured to receive an instrument and to provide a fluid tight seal about the instruments inserted through the orifice. The orifice is in the form of a hole or a piercing. The zero seal is sized and configured to seal when no instrument is in place within the working channel of the tubular member as the zero seal is normally closed (Figures 5A and 5B and lines 6-64 of column 4). The zero seal is coupled or joined to the septum seal due to their positions as shown in Figures 5A and 5B and as disclosed in lines 6-22 of column 4 where Lafontaine discloses that the septum seal and the zero seal can be at a common position in the shaft of the tubular member. The zero seal is also considered to be coupled to the septum seal because the two seals are linked together as they form a seal system together or because they form a pair of seals in the seal system. Even though Lafontaine discloses the device as having a septum seal (140) having an orifice configured to receive an instrument, Lafontaine is silent on the specifics of the septum seal comprising an elastomeric sheet having a frusto-conical shape where the orifice is through the elastomeric sheet. Haberland et al disclose a surgical access device having a septum seal (50) and a zero seal (60) where the zero seal is coupled to the septum seal (paragraphs [0048] and [0049]). The septum seal (50) of Haberland et al comprises an elastomeric sheet having a frusto-conical shape and an orifice (51) through the elastomeric sheet (paragraphs [0043,] [0046] and [0047] and Figures 2, 5, 6, 9A, 10, 11, and 13). The orifice (51) is in the form of a hole or a

piercing. As disclosed in paragraphs [0043] and [0046], the septum seal comprises a sheet which is elastomeric and the septum seal (50) as a whole is disclosed as having an elastic range to readily accommodate the instruments. As seen in Figure 9A, the septum seal comprises an elastomeric sheet having a frusto-conical shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the septum seal of Lafontaine with the septum seal comprising an elastomeric sheet having a frusto-conical shape of Haberland et al as both Lafontaine and Haberland et al disclose a septum seal having an orifice which can be used to provide a seal with instruments which are passed through the orifice and, thus, the septum seal of Haberland et al would be a mere substitution of parts performing the same function. As to claims 75 and 76, the orifice of both Lafontaine and Haberland et al comprises a hole or a piercing.

As to claims 3 and 4, the zero seal is a duckbill seal with an intersecting sealing portion (134A) or a double duckbill seal with two or more intersecting sealing portions (134B) (lines 30-37 of column 4). As to claims 5 and 6, the device has a retaining portion (122) in the form of a flange or a ring at the proximal end of the tubular member (Figure 3). As to claim 7, Lafontaine disclose the tubular member and the septum seal forming a single unit or device (lines 6-22 of column 4) and the limitation of the tubular member and the septum seal being molded together as a single unit is considered to be a product-by-process limitation. A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art. Furthermore, substituting the septum seal of Lafontaine with the

septum seal of Haberland et al would still result in the surgical access device having a tubular member and a septum seal being formed as a single unit or device. As to claim 9, the tubular member, the septum seal, and the zero seal are integrally formed as a single unit because the seals are an integral part of the tubular member and because the tubular member and the seals form a single unit or device (lines 6-22 of column 4). The device also has a placement device (14, 40, 50) as shown in Figures 1, 5B, and 8B). As to claim 21, the placement device is an obturator. As to claim 22, the placement device includes an elongate shaft with a proximal end, a mid-portion, and a distal end. As to claims 23 and 24, the proximal end of the elongate shaft has a handle and the mid-portion of the elongate shaft has a reduced profile (see Figure 1). As to claim 34, the seal has opposing lip portions (132) separated by a slit portion. As to claims 35 and 36, see lines 31-46 of column 4. As to claims 37 and 38, the lip portions are capable of allowing a surgical item such as a surgical suture to extend through the slit portion without disrupting a seal formed by the closure of the opposing lip portions.

As to claim 8, even though Lafontaine discloses the zero seal being coupled to the septum seal, Lafontaine is silent on the specifics of the zero seal being bonded, fused or over-molded with the septum seal. Haberland et al disclose the zero seal (60) being coupled to the septum seal by being bonded, fused, or over-molded with the septum seal (paragraphs [0048] and [0049]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to couple the zero seal to the septum seal of Lafontaine by bonding, fusing, or over-molding as taught by Haberland et al as both Lafontaine and Haberland et al disclose a surgical access device having a

seal system with a zero seal coupled to a septum seal and Haberland et al teach that it is well known to use bonding, fusing, or over-molding to couple the zero seal to the septum seal so that the zero seal and the septum seal can be formed as one unit.

14. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine and Haberland et al as applied to claim 1 above, and further in view of Fischell et al (U.S. Patent No. 6,017,328). Lafontaine and Haberland et al disclose the device substantially as claimed. Even though Lafontaine discloses the device as having an elongate tubular member, Lafontaine is silent of the specifics of the tubular member being formed of an elastomeric material. Fischell et al disclose a surgical access member having an elongate tubular member or cannula section (220) and a septum seal (205) where the tubular member is formed of an elastomeric material (lines 31-34 of column 11 and lines 55-59 of column 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the tubular member of Lafontaine from an elastomeric material as taught by Fischell et al as both Lafontaine and Fischell et al disclose a surgical access device having an elongate tubular member and a seal and Fischell et al teach that it is well known to use an elastomeric material to form the tubular member as this would provide a soft, flexible member to be inserted into a patient's body (lines 48-52 of column 11).

15. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Haberland et al as applied to claim 22 above, and further in view of Green et al (U.S. Patent 6,497,716). Lafontaine in view of Haberland et al disclose the device substantially as claimed. However, Lafontaine is silent on the

specifics of the distal end of the placement device being shaped like an hourglass or comprising a tapered, cone-shaped member. Green et al disclose a placement device (22) which is used to place an access device (14) where the distal end of the placement device is shaped like an hourglass and has a tapered, cone-shaped member. It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the placement device of Lafontaine with the placement device of Green et al as both Lafontaine and Green et al disclose surgical access devices and placement devices for placing the access devices and Green et al disclose that it is well known to use a placement device having a distal end shaped like an hourglass and a tapered, cone-shaped member to place the access device.

16. Claims 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Haberland et al as applied to claim 34 above, and further in view of Willis et al (U.S. Patent No. 6,767,340). Lafontaine in view of Haberland et al disclose the device substantially as claimed. Lafontaine discloses the duckbill seal (130) as having opposing lip portions separated by a slit portion. Haberland also disclose a duckbill seal (60) having opposing lip portions separated by a slit portion (paragraph [0045]). However, Lafontaine and Haberland et al are both silent on the specifics of the opposing lip portions being coated with or attached to a soft or occlusive material providing back pressure forcing the lip portions to close even when the duckbill seal is slightly open. Willis et al disclose a surgical access device (10) having a duckbill seal (42) having an occlusive material (80) attached to the lip portions (70, 72) of the duckbill seal. Willis et al disclose that the occlusive material provides back pressure forcing the

lip portions to close even when the duckbill seal is slightly open as the occlusive member (80) bias the lip portions together in the sealed position (lines 20-35 of column 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the lip portions of the duckbill seal of Lafontaine with an occlusive material as taught by Willis et al as both Lafontaine and Willis et al disclose a surgical device having a duckbill seal with opposing lip portions and Willis et al teach that it is well known to provide the lip portions with an occlusive material to bias the lip portions together in the sealed position. As to claim 36, the occlusive material of Willis et al is silicone as Willis et al disclose that the duckbill seal or valve member (42) is made of silicone (lines 50-57 of column 4). As to claims 37 and 38, the lip portions of both Lafontaine and Willis et al are capable of allowing a surgical item such as a surgical suture to extend through the slit portion without disrupting a seal formed by the closure of the opposing lip portions.

17. Claims 77, 79, 80, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine (U.S. Patent No. 6,520,939) in view of Willis et al (U.S. Patent No. 6,767,340). Lafontaine discloses a surgical access device having an elongate tubular member (110) with a working channel and an axis extending between a proximal end (112) and a distal end (114), a septum seal (140) integrally formed at the distal end of the tubular member, and a duckbill valve (130) positioned distal to the septum seal. As disclosed in lines 46-49 of column 4, the septum seal has an orifice configured to receive an instrument. The duckbill valve has a plurality of opposing lip portions (132) (lines 30-37 of column 4). As shown in Figure 6B, at least two crossing

slits separate the opposing lip portions as the slits extend across or cross from the edge shown at 110 to the center shown at 134B and each slit separates two opposed lip portions. Lafontaine disclose the device substantially as claimed. However, Lafontaine is silent on the specifics of the septum seal comprising an elastomeric seal and the duckbill valve having an occlusive material attached to the opposing lip portions. Willis et al disclose a surgical access device (10) having a septum seal (68) and a duckbill valve having opposing lip portions (70, 72) where an occlusive material (80) is attached to the lip portions (70, 72). The septum seal comprises an elastomeric sheet with an orifice (as shown in Figure 4) through the sheet. The sheet is elastomeric as Willis et al disclose that the valve member (42) is made of a silicone elastomer (lines 50-57 of column 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the septum seal of Lafontaine with the septum seal comprising an elastomeric sheet of Willis et al as both Lafontaine and Willis et al disclose a septum seal having an orifice which can be used to provide a seal with instruments which are passed through the orifice and, thus, the septum seal of Willis et al would be a mere substitution of parts performing the same function. It would also have been obvious to one having ordinary skill in the art at the time the invention was made to provide the lip portions of the duckbill valve of Lafontaine with an occlusive material as taught by Willis et al as both Lafontaine and Willis et al disclose a surgical device having a duckbill seal with opposing lip portions and Willis et al teach that it is well known to provide the lip portions with an occlusive material to bias the lip portions together in the sealed position (lines 20-35 of column 4). As to claim 79, the occlusive

material of Willis et al is silicone as Willis et al disclose that the valve member (42) is made of silicone (lines 50-57 of column 4).

As to claim 80, the duckbill valve of both Lafontaine and Willis et al form a complete seal with a selected item extending through the lip portions (see Figure 5B of Lafontaine and Figure 7 of Willis et al). As to claim 81, the device of Lafontaine has an enlarged retaining flange (122) at the proximal end of the tubular member (Figure 3).

18. Claims 78 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Willis et al as applied to claim 77 above, and further in view of Hart et al (U.S. Patent No. 5,803,919). Lafontaine disclose the device substantially as claimed. Even though Lafontaine disclose two crossing slits separate lip portions, Lafontaine is silent on the specifics of the two crossing slits being arranged at right angles in a single plane. Hart et al disclose a surgical access device (14) having a septum seal (30) and a duckbill valve (32) positioned distal of the septum seal (line 46 of column 3 to line 21 of column 4). The duckbill valve (32) has two crossing slits (103) separating opposed lip portions (61) where the two crossing slits are arranged at right angles in a single plane (Figure 4). The duck bill valve also has a plurality of folds (61a, 61b, 61c, 61d). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the duckbill valve of Lafontaine with two crossing slits separating four opposing lip portions where the two crossing slits are arranged at right angles in a single plane as taught by Hart et al as Lafontaine discloses that the duckbill valve can have a plurality of opposing lip portions and providing the duckbill valve of Lafontaine with the two crossing slits separating four opposing lip

portions where the two crossing slits are arranged at right angles in a single plane would be a mere substitution of the duckbill valve arrangement as shown in Figure 6B of Lafontaine with the duckbill valve arrangement as shown in Figure 4 of Hart et al where both duckbill valve arrangements provide the same function of providing a seal whether an instrument is or is not present through the duckbill valve. As to claim 82, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the duckbill valve of Lafontaine with a plurality of folds as taught by Hart et al as both Lafontaine and Hart et al disclose a surgical access device having a duckbill valve and Hart et al teach that it is desirable to provide the duckbill valve with a plurality of folds to allow the duckbill valve to open more easily when an instrument is passed through the duckbill valve (lines 7-63 of column 5).

19. Claim 83 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lafontaine in view of Willis et al as applied to claim 77 above, and further in view of Haberland et al. Lafontaine discloses the device substantially as claimed. Even though Lafontaine disclose that the septum seal and the duckbill valve can be located at a common position, Lafontaine is silent on the specifics of the septum seal comprising a bonding feature where the duckbill valve is attached to the bonding feature. Haberland et al disclose a surgical access device having a seal system with a septum seal (50) and a duckbill valve (60) where the septum seal comprises a bonding feature (36) and the duckbill valve is attached to the bonding feature (paragraphs [0048] and [0049]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the septum seal of Lafontaine with a bonding feature as taught by

Haberland et al as both Lafontaine and Haberland et al disclose a surgical access device having a seal system with a duckbill coupled to a septum seal by being located at a common position and Haberland et al teach that it is well known to attach the duckbill valve to the bonding feature so that the septum seal and the duckbill valve can be formed as one unit.

Response to Arguments

20. Applicant's arguments with respect to claims 1-9, 20-26, 34-38, 75, and 76 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767